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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/854,356 | 05/09/2001 | Martin A. Cheever | 014058-009811US | 1297 |

20350 7590 05/09/2005

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,356

Applicant(s)

CHEEVER ET AL.

Examiner

MISOOK YU, Ph.D

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113-125 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 116 is/are allowed.
- 6) ☒ Claim(s) 113, 114 and 117-125 is/are rejected.
- 7) ☒ Claim(s) 115 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A (sequence alignment).

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/2005 has been entered.

Claims 113-125 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Specification, Withdrawn

The objection of disclosure is withdrawn in view of the amendment deleting the embedded hyperlink and/or other form of browser-executable code at page 10.

Claim Objections, Withdrawn

The objection of claim 116 is withdrawn in view of the amendment

Claim Rejections - 35 USC § 112, Maintained

Claims 113, 114, and 117-125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

Art Unit: 1642

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is made due to the newly added limitation "at least 90% identity to SEQ ID NO:6" in base claim 113.

Applicant argues that the specification describes the concept of percent identity on page 9, lines 18-26, where it is stated that the percentage is calculated by determining the number of positions at which the identical amino acid residue occurs. The support for 90% could be found on page 10. The specification states that the invention relates to HER-2/neu fusion proteins, compositions comprising the fusion proteins, and method for eliciting or enhancing an immune response to HER-2/neu protein by administering such compositions. See specification on page 3, lines 5, 9-14, and 22-25. In describing the concept of "HER-2/neu fusion protein," the specification states that "variants" are encompassed in this term, for example on page 7, lines 26-29. In turn, the term "variant" is described as "substantially identical" or "substantially similar" to "a fusion protein comprising native (HER-2/neu) polypeptide components." For example page 8, lines 4-6.

These arguments have been fully considered but found unpersuasive because the newly added limitation "the Her-2/new fusion protein comprises at least 90% identity to SEQ ID NO:6" changes the scope of "HER-2/new fusion protein" that was not originally disclosed. The specification at page 9, lines 18-26 as applicant specifically points out in the argument discloses:

"Percentage of sequence identity" is determined by comparing two optimally aligned sequences over a comparison window, wherein the portion of the polynucleotide sequence in the comparison window may comprise additions or deletions (i.e., gaps) as compared to the reference sequence (which does not comprise

additions or deletions) for optimal alignment of the two sequences. The percentage is calculated by determining the number of positions at which the identical nucleic acid base or amino acid residue occurs in both sequences to yield the number of matched positions, dividing the number of matched positions by the total number of positions in the window of comparison and multiplying the result by 100 to yield the percentage of sequence identity.

This disclosure clearly shows that gaps are allowed in the sequence in percentage calculation. Alignment of the instant SEQ ID NO:6 against SEQ ID NO:2 (which includes all of the transmembrane domain) of US PAT 5,869,445 shows SEQ ID NO: 2 of US PAT 5,869,445, which is the native protein of a human HER-2/neu, comprises at least 90% identity to the instant SEQ ID NO:6. Note Exhibit A (sequence alignment). Thus, the new limitation appears to be contradictory to at odd with the other definition of a HER-2/new fusion protein, which is a protein “**consisting** of a HER-2/new extracellular domain fused to a HER-2/new phosphorylation domain”. In addition, the new limitation is contradictory to the definition of the limitation “a HER-2/Neu ECD-PD fusion protein” at the specification at page 7 lines 12 to page 8 lines 16, where it discloses the fusion protein includes any protein as long as the protein does not include a substantial portion of HER2/neu transmembrane domain.

The Following Are New Grounds of Rejection

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) to Application No. 60/117,976, and under 35 U.S.C. 120 to Application No. 09/493,480, filed 05/09/2001 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 113, 114, and 117-125 of this application. The two previous application do not contemplate the claimed invention is directed to method using a polypeptide comprising “at least 90% identity to SEQ ID

Art Unit: 1642

NO:6". Therefore the filing date of the claims claim 113, 114, and 117-125 is the filing date of the instant application, i.e. 09 May 2001

Claim Rejections - 35 USC § 102

Claims 113, 114, 118, 119, and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by US PAT 5,869,445 (02 February 1999).

Claims 113, 114, 118, 119, and 121 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6, wherein the composition is in vaccine (claim 114), along with physiologically acceptable carrier or diluent (claim 118), an oil-in-water emulsion, and an immunostimulatory substance (claim 121).

US PAT 5,869,445 at columns 2, 15, and 16 teaches a method of inducing immune response using a composition, or a vaccine comprising a protein comprising at least 90% identity to instant SEQ ID NO:6 (i.e. SEQ ID NO:2, note the attached sequence alignment, along with physiologically acceptable carrier or diluent, an oil-in-water emulsion, and an immunostimulatory substance.

Claim Rejections - 35 USC § 103

Claims 113, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over D US PAT 5,869,445 (02 February 1999) in view of WO 91/18926.

Claims 113, and 117 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6, wherein the protein is lapidated.

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach the protein being lipidated.

However, WO 91/18926 teaches that lipidation to a protein ensures optimal presentation of an antigen.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to lipidate a protein to stimulate immune response with a reasonable expectation of success.

Claims 113, 119, 120, 122, 123, 124, 124 are rejected under 35 U.S.C. **103(a)** as being unpatentable over US PAT 5,869,445 (02 February 1999) in view of WO95/17210 (filed on 07/02/1996).

Claims 113, 119, 120, 122, 123, 124 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6 in combination with various art-known adjuvants (tocopherol; claim 122, 3D-MPL, QS21, or a combination of 3D-MPL and QS21; claim 123, 3D-MPL and QS21 in an oil-in water emulsion; claim 124, 3D-MPL, QS21 with tocopherol).

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach the protein being the various adjuvants.

However, WO95/17210 teaches that tocopherol, 3D-MPL, QS21, or a combination of 3D-MPL and QS21, 3D-MPL and QS21 in an oil-in water emulsion are well known adjuvants before the effective filing date of the instant application. Note columns 1-4.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use known adjuvants to stimulate immune response with a reasonable expectation of success.

Claims 113, and 125 are rejected under 35 U.S.C. **103(a)** as being unpatentable over US PAT 5,869,445 (02 February 1999) in view of WO 96/02555.

Claims 113, and 125 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6 in combination with CpG-containing oligonucleotides.

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach CpG-containing oligonucleotides.

However, WO 96/20555 teaches (at column 26 lines 15-22) that CpG-containing Oligonucleotides had been known as immune stimulatory molecules before the instant application was filed.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a known immune stimulatory molecules to stimulate immune response with a reasonable expectation of success.

Allowable Subject Matter

Claim 115 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claim 116 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Judy Ladrangan for Art Unit 1642 whose telephone number is 571-272-0536.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MISOOK YU, Ph.D
Examiner
Art Unit 1642

Mon Jan 13 17:52:14 2003

us-09-854-356-6.rat

Page 1

GenCore version 5.1.3
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OM protein - protein search, using sw model

Run on: January 13, 2003, 14:45:15 : Search time 15.7768 Seconds
(without alignments)
1713.883 Million cell updates/sec

Title: US-09-854-356-6

Perfect score: 5078

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Searched: 262574 seqs, 29422922 residues

Total number of hits satisfying chosen parameters: 262574

Minimum DB seq length: 0

Maximum DB seq length: 2000000000

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Listing first 45 summaries

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

| Rank | Score | Query Match | Length | DB ID | Description |
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| 1 | 4900 | 96.5 | 1255 | 2 | US-08-625-101-2 |
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| 3 | 4891 | 96.3 | 1255 | 1 | US-08-467-083-68 |
| 4 | 4891 | 96.3 | 1255 | 1 | US-08-414-4178-68 |
| 5 | 4891 | 96.3 | 1255 | 2 | US-08-486-348A-68 |
| 6 | 4891 | 96.3 | 1255 | 2 | US-08-466-548B-68 |
| 7 | 4891 | 96.3 | 1255 | 2 | US-08-466-680B-68 |
| 8 | 4818 | 94.9 | 1255 | 2 | US-08-484-438-8 |
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| 13 | 3473 | 68.4 | 624 | 4 | US-08-422-734-1 |
| 14 | 1878 | 37.0 | 419 | 4 | US-08-630-155-2 |
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| 16 | 1645 | 32.4 | 1210 | 1 | US-08-475-035-4 |
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| 25 | 1435 | 28.3 | 1342 | 1 | US-07-978-895-4 |
| 26 | 1435 | 28.3 | 1342 | 2 | US-08-484-438-9 |
| 27 | 1435 | 28.3 | 1342 | 2 | US-08-473-119-4 |

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| 28 | 1435 | 28.3 | 1342 | 2 | US-08-475-352-4 | Sequence 4, Appl |
| 29 | 1427.5 | 28.1 | 1343 | 6 | 518384-4 | Patent No. 518384 |
| 30 | 1028.5 | 20.3 | 478 | 4 | US-09-570-454-2 | Sequence 2, Appl |
| 31 | 493 | 9.7 | 97 | 1 | US-08-421-356-3 | Sequence 3, Appl |
| 32 | 493 | 9.7 | 97 | 4 | US-09-046-783-3 | Sequence 3, Appl |
| 33 | 368 | 7.2 | 1382 | 2 | US-08-737-715-2 | Sequence 2, Appl |
| 34 | 313.5 | 6.2 | 1367 | 2 | US-08-625-819-2 | Sequence 2, Appl |
| 35 | 311.5 | 6.1 | 516 | 3 | US-08-746-559A-4 | Sequence 2, Appl |
| 36 | 311.5 | 6.1 | 1367 | 2 | US-08-746-559A-4 | Sequence 2, Appl |
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| 39 | 305.5 | 6.0 | 705 | 2 | US-08-456-447B-4 | Sequence 2, Appl |
| 40 | 305.5 | 6.0 | 705 | 2 | US-08-237-401A-4 | Sequence 2, Appl |
| 41 | 303.5 | 6.0 | 1367 | 4 | US-08-864-641B-18 | Sequence 4, Appl |
| 42 | 293.5 | 5.8 | 486 | 4 | US-08-746-559A-5 | Sequence 18, Appl |
| 43 | 291 | 5.7 | 370 | 4 | US-08-857-076-104 | Sequence 104, App |
| 44 | 269.5 | 5.3 | 541 | 2 | US-08-484-438-6 | Sequence 6, Appl |
| 45 | 267.5 | 5.3 | 1724 | 4 | US-08-857-076-12 | Sequence 12, Appl |

ALIGNMENTS

RESULT 1

US-08-625-101-2

Sequence 2, Application US/08625101

Patent No. 5869445

GENERAL INFORMATION:

APPLICANT: Cheever, Martin A.

TITLE OF INVENTION: COMPOUNDS FOR ELICITING OR ENHANCING IMMUNE

TITLE OF INVENTION: REACTIVITY TO HER-2/neu PROTEIN FOR PREVENTION

TITLE OF INVENTION: OR TREATMENT OF MALIGNANCIES IN WHICH THE HER-2/neu

NUMBER OF SEQUENCES: 4

CORRESPONDENCE ADDRESS:

ADDRESSEE: SEED AND BERRY LLP

STREET: 6300 Columbia Center, 701 Fifth Avenue

CITY: Seattle

STATE: Washington

COUNTRY: USA

ZIP: 98104-7092

COMPUTER READABLE FORM:

MEDIUM TYPE: Floppy disk

OPERATING SYSTEM: IBM PC compatible

SOFTWARE: PatentIn Release #1.0, Version #1.30

CURRENT APPLICATION DATA:

APPLICATION NUMBER: US/08/625,101

FILING DATE: 01-APR-1996

CLASSIFICATION: 424

ATTORNEY/AGENT INFORMATION:

NAME: Sharkey, Richard G.

REGISTRATION NUMBER: 32,629

REFERENCE/DOCKET NUMBER: 920010.448C7

TELECOMMUNICATION INFORMATION:

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TELEFAX: (206) 682-6031

INFORMATION FOR SEQ ID NO: 2:

SEQUENCE CHARACTERISTICS:

LENGTH: 1255 amino acids

TYPE: amino acid

TOPOLOGY: linear

MOLECULE TYPE: protein

US-08-625-101-2

Query Match 96.5% Score 4900: DB 2: Length 1255;

Best Local Similarity 73.2%: Pred. No. 0:

Matches 919: Conservative 0: Mismatches 0: Indels 316: Gaps 1:

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Page 2

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 1021 EBYLVPOGFPFCDPAAGAGVYHNRHSSSTRSGGDLTGLERPESEARSPSLAPSEG 1080
 1021 EBYLVPOGFPFCDPAAGAGVYHNRHSSSTRSGGDLTGLERPESEARSPSLAPSEG 1080
 745 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 804
 745 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 804
 745 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 804
 1081 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 1140
 1081 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 1140
 1081 AGSVFPGDGLGMAAGGLSLPTHDSPLORSSEDPYRLSERPDGYAPATCSPOREYV 1140

805 NOPDVRPPSPREGPLDPAAPACATILBRKTLSPGKNGVYKRVFAGCAVENPEYLTPRO 864
 1141 NOPDVRPPSPREGPLDPAAPACATILBRKTLSPGKNGVYKRVFAGCAVENPEYLTPRO 1200
 865 GGAAPQPPPPAFSPAFNDLYYMDODPERGAPSPSTFKGTPAENPEYLGIDVPV 919
 1201 GGAAPQPPPPAFSPAFNDLYYMDODPERGAPSPSTFKGTPAENPEYLGIDVPV 1255

RESULT 2
 US-08-356-786-2
 Sequence 2, Application US/08356786
 Patent No. 5877305

GENERAL INFORMATION:
 APPLICANT: Huxton, James S.
 APPLICANT: Oppermann, Hermann
 APPLICANT: Houston, L. L.
 APPLICANT: Rung, David B.
 TITLE OF INVENTION: Biosynthetic Binding Protein for Cancer
 NUMBER OF SEQUENCES: 16
 CORRESPONDENCE ADDRESS:
 ADDRESSEE: Edmund R. Pitcher, Teesta, Hurwitz, & Thibault
 STREET: Exchange Place, 53 State Street
 CITY: Boston
 STATE: Massachusetts
 COUNTRY: USA
 ZIP: 02109
 COMPUTER READABLE FORM:
 MEDIUM TYPE: Floppy disk
 COMPUTER: IBM PC compatible

SOFTWARE: Patentin Release #1.0, Version #1.25
 CURRENT APPLICATION DATA: US/08/356,786
 APPLICATION NUMBER: US/08/356,786
 FILING DATE: 07/831,967

CLASSIFICATION: 424
 PRIOR APPLICATION DATA:
 APPLICATION NUMBER: 07-FEB-1992
 FILING DATE: 06-FEB-1992
 ATTORNEY/AGENT INFORMATION:
 NAME: Pitcher, Edmund R.
 REGISTRATION NUMBER: 27,829
 REFERENCE/DOCKET NUMBER: CRP-053
 TELECOMMUNICATION INFORMATION:
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INFORMATION FOR SEQ ID NO: 2:
 SEQUENCE CHARACTERISTICS:
 LENGTH: 1255 amino acids
 TYPE: amino acid
 TOPOLOGY: linear
 MOLECULE TYPE: protein
 US-08-356-786-2

Query Match 96.5% Score 4900; DB 2; Length 1255;
 Best Local Similarity 73.2% Pred. No. 0;
 Matches 919; Conservative 0; Mismatches 0; Indels 336; Gaps 1;

1 MELALACRMGLIALLPRAASTOVCTGDKILRLPASPEHNDMLNLYOGCOVVOGML 60
 1 MELALACRMGLIALLPRAASTOVCTGDKILRLPASPEHNDMLNLYOGCOVVOGML 60
 61 ELYLPTNASTLSFLODIOEVGYVLIANNOVROVLORLRIVGTOLFEEDNALAVLNDG 120
 61 ELYLPTNASTLSFLODIOEVGYVLIANNOVROVLORLRIVGTOLFEEDNALAVLNDG 120
 121 DPLNNTPTVYASPGSLRELOLRSLEILKGVLIORNPOLCYODTILMKDIFHNKNOA 180
 121 DPLNNTPTVYASPGSLRELOLRSLEILKGVLIORNPOLCYODTILMKDIFHNKNOA 180
 121 DPLNNTPTVYASPGSLRELOLRSLEILKGVLIORNPOLCYODTILMKDIFHNKNOA 180
 181 LTLIDTNRSRACHPCSPCKSGRCSESSSECCOSLTFTVAGCAGCARKGFLPDCCHEC 240
 181 LTLIDTNRSRACHPCSPCKSGRCSESSSECCOSLTFTVAGCAGCARKGFLPDCCHEC 240
 181 LTLIDTNRSRACHPCSPCKSGRCSESSSECCOSLTFTVAGCAGCARKGFLPDCCHEC 240